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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,696	05/29/2001	Glenn G. Strawder		5731
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William D. Hall 10850 Stanmore Drive Potomac, MD 20854-1522			EXAMINER PORTER, RACHEL L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/865,696

Applicant(s)

STRAWDER, GLENN G.

Examiner

RACHEL L. PORTER

Art Unit

3626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/15/09.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- _____ Paper No(s)/Mail Date _____

- 4) ☒ Interview Summary (PTO-413)
- _____ Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 1/15/09. Claims 65-80 are pending.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/7/08 has been entered.

Response to Amendment

3. The Declaration under 37 CFR 1.132 filed 10/16/08 is insufficient to overcome the rejection of claim 66-72,77 - based upon Howson, Prince and Dorne as set forth in the last Office action because the facts presented regarding applicant's background and experience are not germane to the applied rejection. In particular, the Applicant's Declaration refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the

objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

4. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 65-68, 83,84,87 and 91,93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As per claim 65-68, 83,84,87 and 91, it is unclear whether the applicant intends to claim a system or a method the prescription creation system. While the preamble the recites a system comprising, the body of the claim list both system components and method steps.

For example, in claim 65, the claim recites "said computer comparing said first steps with said second steps...."; "said computer computer comparing at least one step of said first series of steps...."(claim 67); "said computer compares the cost of performing said first series of steps.... (claim 91). These steps actively describe steps the computer is performing (e.g. as a method/process) rather defining the functionality the system/ computer is configured to perform.

In IPXL Holdings, L.L.C. v Amazon.Com, Inc. (CAFC, 05-1009, -1487,

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11/21/2005), the court held a claim covering two statutory classes to be properly rejected under 112,2nd paragraph:

Whether a single claim covering both an apparatus and a method of use of that apparatus is invalid is an issue of first impression in this court. The Board of Patent Appeals and Interferences ("Board") of the PTO, however, has made it clear that reciting both an apparatus and a method of using that apparatus renders a claim indefinite under section 112, paragraph 2. *Ex parte Lyell*, 17 USPQ2d 1548 (BPAI 1990). As the Board noted in *Lyell*, "the statutory class of invention is important in determining patentability and infringement." *Id.* at 1550 (citing *In re Kuehl*, 475 F.2d 658, 665 (CCPA 1973); *Rubber Co. v. Goodyear*, 76 U.S. 788, 796 (1870)). The Board correctly surmised that, as a result of the combination of two separate statutory classes of invention, a manufacturer or seller of the claimed apparatus would not know from the claim whether it might also be liable for contributory infringement because a buyer or user of the apparatus later performs the claimed method of using the apparatus. *Id.* Thus, such a claim "is not sufficiently precise to provide competitors with an accurate determination of the 'metes and bounds' of protection involved" and is "ambiguous and properly rejected" under section 112, paragraph 2. *Id.* at 1550-51. This rule is well recognized and has been incorporated into the PTO's Manual of Patent Examination Procedure. § 2173.05(p)(II) (1999) ("A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph."); see also Robert C. Faber, *Landis on Mechanics of Patent Claim Drafting* § 60A (2001) ("Never mix claim types to different classes of invention in a single claim.").

Claims 66-68, 83,84,87 and 91 inherit the deficiencies of claim 65 through dependency and are also rejected.

Regarding claim 93, claim 76 has been cancelled. Therefore, it is unclear which independent limitations claim 93 is intended to incorporate. Examiner will interpret claim as dependent from 77.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 65,67-69,71-73, and 76-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al (USPN 5,088,981) in view of Prince (US 5417213) [claim 65] Howson et al discloses an apparatus for monitoring the operations of an operator of a machine that performs a medical function, comprising:

- a computer for storing (col. 6, lines 27-36) a first series of steps (e.g. standard protocol of operations) that an operator should perform when using said machine to perform said medical function, (col. 6, lines 60-68; col. 12, lines 13-38)
- said computer also storing a second series of steps that set forth what the operator of said machine performed during the use of the machine to perform said medical function, (col. 8, lines 58-68; col. 12, lines 13-38)
- said computer including a program for comparing said first series of steps (standard protocol) with said second series of steps (col. 8, lines 58-68— monitoring compliance of patient with prescribed delivery schedule)

Howson discloses an apparatus as outlined above, but discloses that it is an infusion pump, not an imaging device. Prince discloses a system wherein the apparatus includes an infusion pump and a medical imaging device. (col. 12, lines 9-36) At the

time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Howson with the teaching of Prince to combine an infusion system with an MRI system (a machine which takes pictures of a part of the body.) As suggested by Prince, one would have been motivated to include this feature to facilitate proper or desired timing between the injection of the magnetic resonance agent and the acquisition of image data, in addition to providing proper rates of infusion of the contrast agent. (col. 12, lines 19-25).

[claims 67-68] Howson and Prince disclose the apparatus of claim 65 with an imaging component (i.e. to take pictures of body parts) as explained in the rejection of claim 65. Howson also discloses providing a computer with a memory, (col. 6, lines 27-36) providing said memory with a standard protocol for operating said machine to perform a medical function, (col. 6, lines 60-68; col. 12, lines 13-38); and providing an operator for operating said machine.

Howson does not expressly disclose a method in which there are a plurality of machines each of which perform a medical function, plural operators for operating said machines, providing computer comparisons of said standard protocol with the operations of each operator. Furthermore, Howson does not disclose the step of providing at least one computer for each machine of the plurality of machines.

However, at the time of the applicant's invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of Howson to include a plurality of machines each of which perform a medical function, plural operators for operating said

machines, providing computer comparisons of said standard protocol with the operations of each operator and providing at least one computer for each machine of the plurality of machines. (Multiplication or duplication of parts for multiple effects is an obvious modification over the prior art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8, 11; 549 F.2d 833 (7th Cir. 1977); *In re Harza*, 124 USPQ 378, 380; 274 F.2d 669 (CCPA 1960)) One would have been motivated to include this feature to increase the efficiency of the system, by allowing more than one operator to work at one time.

[claim 69] Howson discloses a method of monitoring the operations of an operator of a medical machine which gathers medical information about a patient, comprising:

- providing a computer with a memory, (col. 6, lines 27-36)
- storing in said computer a predetermined series of steps (e.g. standard protocol of operations) for operating said machine to perform a medical function, (col. 6, lines 60-68; col. 12, lines 13-38)
- entering into said memory the actual series of steps of said operator in operating said machine, (col. 8, lines 58-68; col. 12, lines 13-38)
- comparing said predetermined series of steps with said actual series of steps by said operator. (col. 8, lines 58-68)

Howson discloses a method as outlined above, but discloses that it is an infusion pump, not an imaging device. Prince discloses a system and system wherein the apparatus includes an infusion pump and a medical imaging device. (col. 12, lines 9-36) At the time of the applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the method and system of Howson with the teaching of Prince to combine an infusion system with an MRI system (a machine which takes pictures of a part of the body.) As suggested by Prince, one would have been motivated to include this feature to facilitate proper or desired timing between the injection of the magnetic resonance agent and the acquisition of image data, in addition to providing proper rates of infusion of the contrast agent. (col. 12, lines 19-25).

[claim 71] Howson discloses the method of claim 65 as explained in the rejection of claim 65. Howson also discloses providing a computer with a memory, (col. 6, lines 27-36) providing said memory with a standard protocol for operating said machine to perform a medical function, (col. 6, lines 60-68; col. 12, lines 13-38); providing an operator for operating said machine, (col. 8, lines 58-68; col. 12, lines 13-38) and providing comparisons by said computer which compare said standard protocol and said operations of said operator. (col. 8, lines 58-68).

Howson does not expressly disclose a method in which there are a plurality of machines each of which perform a medical function, plural operators for operating said machines, providing computer comparisons of said standard protocol with the operations of each operator. Furthermore, Howson does not disclose the step of providing at least one computer for each machine of the plurality of machines.

However, at the time of the applicant's invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of Howson to include a plurality of machines each of which perform a medical function, plural operators for operating said

machines, providing computer comparisons of said standard protocol with the operations of each operator and providing at least one computer for each machine of the plurality of machines. (Multiplication or duplication of parts for multiple effects is an obvious modification over the prior art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8, 11; 549 F.2d 833 (7th Cir. 1977); *In re Harza*, 124 USPQ 378, 380; 274 F.2d 669 (CCPA 1960)) One would have been motivated to include this feature to increase the efficiency of the system, by allowing more than one operator to work at one time.

[claim 72] Howson discloses a method as defined in claim 65, in which said computer provides information on procedures performed on said machines as well as summaries of the operations of the machine. (col. 8, line 58-68; col. 12, lines 53-66) Howson does not expressly disclose that this step is performed for a plurality of computers or machines.

However, at the time of the applicant's invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of Howson to include a plurality of machines and a plurality of computer comparisons/ summaries for each machine and the operations performed on the machines. (Multiplication or duplication of parts for multiple effects is an obvious modification over the prior art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8, 11; 549 F.2d 833 (7th Cir. 1977); *In re Harza*, 124 USPQ 378, 380; 274 F.2d 669 (CCPA 1960)) One would have been motivated to include this feature to increase the efficiency of the system, by allowing more than one operator to work at one time.

[claims 83-91] Howson discloses the method of monitoring the work of an operator of a medical machine comprising:

- a computer, (col. 6, lines 27-36)
- entering into a memory data which represents at least 2 predetermined series of steps of said operator in operating during use of said machine with each such entry occurring prior to the next operation of said machine undertaken by said operator, and (col. 8, lines 58-68)
- means for entering into said computer means the actual series of steps of said operator in operating said machine, (col. 8, lines 58-68; col. 12, lines 13-38)
- means for comparing said entries into said computer means actual steps with said predetermined series of steps. (col. 8, lines 58-68; col. 12, lines 44-66)

Howson discloses a method as outlined above, but discloses that it is an infusion pump, not an imaging device. Prince discloses a system and system wherein the apparatus includes an infusion pump and a medical imaging device. (col. 12, lines 9-36) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method and system of Howson with the teaching of Prince to combine an infusion system with an MRI system (a machine which takes pictures of a part of the body.) As suggested by Prince, one would have been motivated to include this feature to facilitate proper or desired timing between the injection of the magnetic resonance agent and the acquisition of image data, in addition to providing proper rates of infusion of the contrast agent. (col. 12, lines 19-25).

[claim 77] The limitations of claim 77 are addressed by the rejection of claims 65 and and incorporated herein.

9. Claims 66, 70,92,93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson and Prince in view of Dorne (USPN 5,325,293).

[claim 66] Howson and Prince disclose the apparatus as defined in claim 65, as explained in the rejection of claim 65. However, Howson does not disclose an apparatus in which said computer has an output which sets forth prices computed from the operations performed by said machine.

Dorne discloses an apparatus in which a computer has an output which sets forth prices computed from the operations performed by said machine. (i.e. determining how many of a particular examination have been performed and determining how much money a particular number of examinations produce) (col. 9, lines 53-60; col. 15, lines 60-co1.16, line 19) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the apparatus of Howson and Prince in combination with the teaching of Dorne to provide output on the prices computed from operations performed by a machine. As suggested by Dorne, one would have been motivated to include this feature to provide physicians and medical personnel with billing information without requiring them to have a thorough understanding of the complex nomenclature used in the CPT coding system (col. 3, lines 1-15).

[claim 70,92] Howson and Prince disclose the apparatus as defined in claim 65, as explained in the rejection of claim 65. However, Howson does not disclose an apparatus in which said computer has an output which sets forth prices computed from the operations performed by said machine.

Dorne discloses an apparatus in which a computer has an output which sets forth prices computed from the operations performed by said machine. (i.e. determining how many of a particular examination have been performed and determining how much money a particular number of examinations produce) (col. 9, lines 53-60; col. 15, lines 60-co1.16, line 19) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the apparatus of Howson and Prince in combination with the teaching of Dorne to provide output on the prices computed from operations performed by a machine. As suggested by Dorne, one would have been motivated to include this feature to provide physicians and medical personnel with billing information without requiring them to have a thorough understanding of the complex nomenclature used in the CPT coding system (col. 3, lines 1-15)

[claim 93] Howson and Prince disclose the apparatus as defined in claim 77, as explained in the rejection of claim 77. However, Howson does not disclose an apparatus in which said computer records series of physical stops in performing a procedure, the cost of each step and the cost of each step and the total of all of the costs.

Dorne discloses an apparatus in which said computer records series of physical stops in performing a procedure, the cost of each step and the cost of each step and the total of all of the costs.

. (i.e. determining how many of a particular examination have been performed and determining how much money a particular number of examinations produce) (col. 9, lines 53-60; col. 15, lines 60-co1.16, line 19) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the apparatus of Howson and Prince in combination with the teaching of Dorne to provide output on the prices computed from operations performed by a machine. As suggested by Dorne, one would have been motivated to include this feature to provide physicians and medical personnel with billing information without requiring them to have a thorough understanding of the complex nomenclature used in the CPT coding system (col. 3, lines 1-15)

The method as defined in claim 76, in which said computer records series of physical stops in performing a procedure, the cost of each step and the cost of each step and the total of all of the costs.

Response to Arguments

10. Applicant's arguments with respect to claims 65-80 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571)272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, (Christopher) Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. P./
Examiner, Art Unit 3626

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626